

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action dated 18 December 2002 are respectfully requested. A separate petition for a two-month extension of time accompanies this amendment.

In the present Office Action, the Examiner rejected claims 32, 35, 36, 65, 66, 68, 74-76, 78-85, 87, 88, 92, and 98 as anticipated by Yoon U.S. Patent 5,707,362 ("Yoon"); rejected claims 32, 35, 36, 65-67, and 74 as anticipated by Colvin et al. U.S. Patent 4,936,823 ("Colvin"); rejected claims 33 and 34 as obvious over Yoon. The Examiner also allowed claims 93-97 and 99 and objected to claims 70-73, 86, 90, and 91, but indicated they would be allowable if rewritten in independent form. The undersigned respectfully submits that the present claims are patentable over Yoon and Colvin.

I. Amendments

The present amendment amends claims 32, 67, and 83. The amendment to claim 67 is a minor change to ensure consistency of language with amended claim 32. Claim 83 has been amended to more broadly recite a "manually engageable member" instead of a "manually engageable ring." The specification has also been amended to reflect issuance of the parent application.

As filed, the specification of the present application included a series of headings. When the present application was published as U.S. Publication No. 2001/0018594 (the "Published Application"), these headings were run together with the next paragraph of the specification. The undersigned wanted to make sure that this error was rectified prior to issuance of the current application, but is not too sure how to go about doing so. The present amendments to pages 9-28 of the specification technically simply reflect the text of the application as originally filed, but are marked to show a return between the heading and the subsequent paragraph as a change to reflect correction of the specification as published in the Published Application.

II. **Claims 32-36, 65, 66, 68, 74-76, 78-85, 87, 88, 92, and 98 are patentable over Yoon**

Yoon suggests using a trocar and cannula to access an anatomical cavity, e.g., the abdominal cavity. The Examiner points to the penetrating instrument 20 shown in Figures 1-7 as anticipating many of the claims in the present application. This penetrating instrument 20 includes a cannula 26 that receives a trocar or "penetrating unit 24." A middle member 32 carrying a series of flexible strips 44 is disposed between the cannula 26 and the trocar 24. There is no connection between the trocar 24 and this middle member 32.

Figures 1, 6, and 7 of Yoon illustrate a sequence of stages to introduce the penetrating instrument 20 into an anatomical cavity, as discussed in the specification at column 9, line 35-column 10, line 9. In use, the operator simply advances the trocar and cannula through the tissue wall W. The force of the tissue around the flexible strips 44 will cause the flexible strips to compress (Figure 6). Once the strips 44 pass through the tissue wall W into the anatomical cavity, they will automatically expand (Figure 7) under the force of a spring 45 (Figure 1). Yoon focuses on this automatic feature in the Summary of the Invention:

Some of the advantages of the present invention are that anchoring of a penetrating instrument relative to an anatomical cavity wall can be achieved without the need for intervention by the surgeon to actuate the anchoring member upon penetration into the anatomical cavity, that movement of a safety member to the extended protruding position and/or retraction of a penetrating member, as well as automatic anchoring of the penetrating instrument, can be accomplished simultaneously...

A. **Claims 32-36, 65-68, and 74**

Claim 32, as amended, calls for at least one anchor member having a free distal end. When the specified portion of the elongate member is in its second position, the at least one anchor member projects through at least one aperture in the elongated tube and extends transversely with the free distal end positioned outwardly of the elongate tube. In Yoon, the strips 44 are connected at one end to the main body of the middle member 32 and at the other end to a ring at the distal end 46. Consequently,

none of these strips 44 includes a free distal end. Accordingly, claim 32 is distinguishable from Yoon.

The undersigned further submits that claim 32 is unobvious over Yoon. As noted above, the penetrating instrument 20 upon which the Examiner relies is specifically designed to automatically deploy. To accomplish this function, the strips 44 have a tapered profile that allows the tissue wall to collapse the strips during introduction of the device. It is unclear to the undersigned how this functionality could be maintained if the strips 44 had a free distal end positioned outwardly of the cannula 26, for example. Even if it were theoretically possible to modify Yoon in this fashion, such a mere possibility is insufficient to support a *prima facie* rejection under 35 U.S.C. § 103:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.

MPEP § 2143.01. The MPEP goes on to specifically state that any proposed modification of a prior art reference that would change its principal of operation – e.g., modifying Yoon's penetrating instrument 20 so the strips 44 have free distal ends – is an insufficient basis for a *prima facie* obviousness rejection. As a consequence, claim 32 is believed to patentably define over Yoon. Claims 33-36, 65, 66, 68, and 74 all depend from claim 32 and are believed to be patentable at least by virtue of their dependence from an allowable base claim.

B. Claims 75, 76, 78, 79, and 82

Claim 75 recites, among other features, a manually controllable actuator comprising an elongate member sized for a close sliding fit within the central bore of an elongate tube, with the actuator being movable with respect to the elongate tube between a first position and a second position. Each of a plurality of manually deployable anchor members is operatively connected to the actuator so that each anchor member assumes a retracted position when the actuator is in the first position and assumes an extended position when the actuator is in its second position. Each

anchor member in its extended position projects outwardly from its associated aperture in the elongate tube into the tissue mass and assumes a curved configuration to facilitate stabilization of the tissue mass.

Claim 75 is readily distinguishable from the penetrating instrument 20 on which the Examiner relies in his rejection. As stated in the current Office Action, the Examiner considers the trocar 24 to be the claimed "manually controllable actuator" and contends that the strips 44 are "manually deployable anchor members that are operatively connected to this actuator" such that the anchor members assume their retracted position or an extended position depending on the position of this "actuator." As noted above, though, there is no connection between the trocar 24 and the strips 44 or the middle member 32. In deploying the penetrating instrument 20, the force of the tissue against the strips 44, not the position of the trocar 24, causes the strips 44 to collapse as shown in Figure 6. The purpose of Yoon's penetrating instrument 20 is to provide a cannula for access to the anatomical cavity, e.g., to allow endoscopic procedures. This necessarily requires complete removal of the trocar 24, but the position of the strips 44, as shown in Figure 7, does not change when the trocar 24 is removed, highlighting the independence of the movement of these strips 44 from the trocar 24.

Furthermore, claim 75 indicates that each anchor member in its extended position projects outwardly from its associated aperture into the tissue mass. The basic premise of operation of Yoon's device dictates that the strips 44 expand only after they are no longer in the tissue of the wall W. As a matter of fact, the strips 44 of the penetrating instrument 20 collapse under the force of this tissue and the penetrating instrument 20 would not work as explained if these strips 44 were designed to project outwardly into the tissue of the wall W.

In light of the above, the undersigned respectfully submits that claim 75 is not anticipated by Yoon. Nothing in Yoon would lead those skilled in the art to directly contradict Yoon's detailed instructions and arrive at the invention of claim 75. Consequently, claim 75 is patentable over Yoon. Claims 76, 78, 79, and 82 all depend from claim 75 and are believed to be allowable at least because they depend from an allowable base claim.

C. Claims 80 and 81

Claim 80 calls for a tissue anchor that includes, *inter alia*, a manually controllable actuator comprising an elongate member slidably received within the central bore of an elongate tube, with the actuator being movable with respect to the elongate tube between a first position and a second position. A plurality of manually deployable anchor members are attached to the elongate member for movement therewith such that each anchor member assumes a retracted position when the actuator is in its first position and each anchor assumes an extended position when the actuator is in its second position. In its extended position, each anchor member projects outwardly from its associated aperture into the tissue mass and assumes a curved configuration to facilitate stabilization of the tissue mass.

Some aspects of claim 80 are analogous to aspects of claim 75. By analogy to the preceding discussion of claim 75, therefore, the undersigned respectfully submits that claim 80 and dependent claim 81 are patentable over Yoon.

D. Claims 83-85, 87 and 88

Claim 83 generally recites an elongate tube and a rod having a length slidably received in a central bore of an elongate tube. Each of four anchor members is connected to the rod for movement therewith such that each anchor member assumes a retracted position when the rod is in a first position and assumes an extended position when the rod is in a second position. In its extended position, each anchor member projects outwardly from an aperture in the elongate tube into a tissue mass and assumes a curved configuration to facilitate stabilization of the tissue mass.

Aspects of claim 83 are analogous to aspects of claim 75. By analogy to the preceding discussion of claim 75, therefore, the undersigned respectfully submits that claim 83 is patentable over Yoon. Claims 84, 85, 87, and 88 all depend from claim 83 and are believed to be patentable at least by virtue of this dependence.

E. Claim 92

Claim 92 recites, among other elements, a rod having a length which is slidably received in a central bore of an elongate tube and four anchor members. Each of the anchor members is connected to the rod for movement therewith such that when the rod is moved distally each anchor member moves outwardly from an aperture in the elongate tube into a tissue mass to assume a curved configuration to facilitate stabilization of the tissue mass.

Aspects of claim 92 are analogous to aspects of claim 75. By analogy to the preceding discussion of claim 75, therefore, claim 92 is believed to be patentable over Yoon.

F. Claim 98

Claim 98 calls for a tissue anchor that includes, among other elements, a manually controllable actuator that is movable with respect to an elongate tube and includes a stop that cooperates with the elongate tube to limit movement and define a second position of the actuator. Each of a plurality of manually deployable anchor members is operatively connected to the actuator. When the actuator is in its second position, each anchor assumes an extended position in which it projects outwardly from an aperture in the elongate tube into the tissue mass and assumes a curved configuration to facilitate stabilization of the tissue mass.

Aspects of claim 98 are analogous to aspects of claim 75. By analogy to the preceding discussion of claim 75, the undersigned respectfully submits that claim 98 is patentable over Yoon.

III. Claims 32, 35, 36, 65-67, and 74 are patentable over Colvin

Colvin suggests an implantable capsule that can be used to deliver therapeutic treatment (e.g., radiation or chemotherapy) to a tumor. This implant capsule 10 includes a body member 12 having a bore 22 and a series of slots 16. A central stem 20 is locked in place in the central bore 22. A series of arms 18 are attached to this locked central stem. During deployment, the stem 20 may be grasped with forceps 34

and a separate catheter 36 is used to collapse the arms toward the center of the bore 22. When the device is in place, it is implanted by withdrawing the catheter, allowing the arms 18 to expand. Thereafter, the forceps may be detached, leaving the stem 20 and the rest of the implant capsule 10 in place.

Claim 32 requires an elongate member having a portion sized for receipt and axial movement in a central bore of an elongate tube between a first position and a second position. At least one anchor member is attached to that portion of the elongate member. When the elongate member is in a first position, the at least one anchor member is at least partially received in the elongate tube. When the portion is in a second position, the at least one anchor member projects through at least one aperture.

In the Office Action, the Examiner pointed to the stem 20 as the claimed elongate member, noting that the arm members 18 are attached to the stem. The Examiner does not contend, however, that the stem 20 can be moved between a first position and a second position and that the positions of the arms 18 in relation to the elongate tube may change as a result of such movement. As undersigned sees no such suggestion in Colvin, the undersigned respectfully submits that claim 32 is distinguishable from Colvin under 35 U.S.C. § 102.

The undersigned further submits that claim 32 is patentable over Colvin under 35 U.S.C. § 103. The arms 18 of Colvin's implant capsule 10 are intended to be left behind with the rest of the implant capsule 10 when the delivery forceps 34 and catheter 36 are withdrawn. For this reason, the arms 18 are attached to the central stem 20, which is affixed to the body 12 of the implant capsule 10. The entire deployment system, i.e., the forceps 34 and catheter 36, must be detachable from the implant capsule 10, including the arms 18, to allow the implant capsule to be left behind. Movement of the arms 18 is controlled by sliding the catheter over the central stem 20 or withdrawing the catheter proximally.

Nothing in Colvin would lead one of ordinary skill in the art to make the central stem 20 slidable with respect to the body 12 to control deployment of the arms. To the

contrary, having the central stem affixed to the body 12 is important to allow the body 12 to be implanted in a fixed location so the radiation or chemotherapy remains in the tumor instead of migrating to healthy tissue. Allowing relative movement between this stem 20 and the body 12 would, at best, unnecessarily complicate this fixation function. The catheter 36 does cause the position of the arms 18 to change as the catheter is moved proximally or distally. Attaching the arms 18 to the catheter 36, however, would prevent the arms 18 from holding the implant capsule 10 in place after the catheter 36 is withdrawn.

In light of the above, the undersigned respectfully submits that claim 32 is patentable over Colvin. Claims 35, 36, 65-67 and 74 all depend from claim 32 and are believed to be patentable at least by virtue of their dependence from an allowable base claim.

IV. Conclusion

In view of the foregoing, the claims pending in the application comply with the requirements of 35 U.S.C. § 112 and patentably define over the applied art. A Notice of Allowance is, therefore, respectfully requested. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (206) 264-3848.

Respectfully submitted,

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